

# “VICTOR BABEȘ” UNIVERSITY OF MEDICINE AND PHARMACY TIMIȘOARA

## University Clinic of Periodontology

### INFORMED CONSENT FORM FOR CLINICAL STUDY PARTICIPANT

#### Study Title

**Effect of temporary composite-bonded wire splinting on the proportion of sites reaching therapeutic endpoints after surgical Step 3 of periodontal therapy in advanced (stage IV) periodontitis patients: a randomized controlled trial**

#### 1. Purpose of the study

The purpose of this study is to evaluate whether temporary stabilization through splinting of anterior mandibular teeth influences clinical outcomes obtained after periodontal surgical treatment (Step 3 of periodontal therapy) in patients with stage IV periodontitis.

#### 2. Study procedure

Participants will be randomly allocated to:

1. **Splinting group:** A temporary dental splint will be applied to the lingual (inner) surface of the anterior mandibular teeth before periodontal surgical intervention.
2. **Non-splinting group:** No dental splint will be applied before periodontal surgical intervention.

The dental splint is made of a thin stainless steel wire, fixed to the teeth with composite material.

If you agree to participate, the treatment and monitoring will be conducted in the **following stages:**

**Stage 1 (Initial Visit):** Complete periodontal re-evaluation, professional removal of dental plaque, and personalized oral hygiene instructions.

**Stage 2 (for participants with splinting):** Application of temporary dental splint on the lingual surface of anterior mandibular teeth, approximately one week before surgical intervention.

**Stage 3:** Periodontal surgical intervention (Step 3 of periodontal therapy), performed according to clinical indication.

**Stage 4 (monitoring):** Follow-up visits at approximately 2 weeks, 2 months, 4 months, and 6 months after surgical intervention, which include clinical examinations, professional cleaning, and evaluation of postoperative progress.

The total duration of your participation in the study is approximately **6-8 months**.

#### 3. Possible risks and inconveniences

Participation in this study does not involve additional risks beyond standard periodontal treatments. However, the following situations may occur:

- Discomfort, pain, or inflammation associated with periodontal surgical intervention—normal reactions for this type of treatment, for which you will receive clear instructions and be monitored;
- Transient sensation of tension or discomfort after splint application;
- Difficulties with interdental hygiene, for which you will receive detailed instructions;
- Partial debonding or fractures of composite material, which may occur occasionally and can be easily remedied without invasive procedures.

#### **4. Potential benefits**

Participation in this study may bring you the following benefits:

- Temporary stabilization of mobile teeth;
- Creation of more favorable conditions for healing after periodontal surgical intervention;
- Careful clinical monitoring throughout the study duration.

#### **5. Data confidentiality**

Your personal data will be coded and anonymized. Your name will not appear in any report or publication resulting from this study. Access to information will be limited to the research team. All data will be managed in accordance with personal data protection regulations. The collected data (clinical, photographic, digital) will be stored in a secure format. **Anonymized and protected data may be used subsequently for scientific purposes, exclusively for future ethically approved studies, without the possibility of identifying participants.**

Results will be presented in scientific publications or professional events, without allowing individual identification of participants.

#### **6. Participant rights**

- Participation is completely voluntary.
- You may refuse to participate or withdraw at any time, without consequences for your treatment.
- Withdrawal will not affect your relationship with medical staff or the institution.
- You have the right to ask questions and receive clarifications at any time during the study.

#### **7. Contact person**

For questions or additional information, you may contact:

**Principal Investigator:** Prof. Dr. Dr. med. dent. Ștefan Ioan Stratul  
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**Study Coordinator:** PhD candidate Dr. Alla Belova  
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### **8. Participant’s Declaration**

I have read and understood the above information regarding participation in this clinical study. I have had the opportunity to ask questions and have received clear and satisfactory answers. I understand that participation is voluntary and that I may withdraw at any time, without consequences. By signing, I express my free and informed consent to participate in this study.

Participant Name    Signature    Date

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### **9. Investigator’s Declaration**

I declare that I have provided the participant with all relevant information, in clear and accessible language, and that I have answered all their questions.

Investigator Name    Signature    Date

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